

Citation:

Fung TT, Schulze M, Manson JE, Willett WC, Hu FB. Dietary patterns, meat intake, and the risk of type 2 diabetes in women. *Arch Intern Med*. 2004;164(20):2235-2240.

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Study Design:

Prospective cohort study

Class:

B - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the association between major dietary patterns and risk of type 2 diabetes among women in the ongoing Nurses' Health Study (NHS) cohort

Inclusion Criteria:

- Fewer than 70 missing items in the 1984 Food Frequency Questionnaire (FFQ)
- A total caloric range between 500 and 3,500 kcal/d

Exclusion Criteria:

- Women with a history of cancer, cardiovascular disease and diabetes

Description of Study Protocol:**Recruitment**

- The NHS began in 1976, when female nurses 30 to 55 years living in 11 U.S. states responded to a questionnaire regarding medical, lifestyle, and other health related information. Since then, questionnaires have been sent biennially. The FFQ was first included in 1980 questionnaire and expanded in 1984.

Design

- 14-year follow-up prospective cohort study from 1984 to 1998

Blinding used (if applicable)

not described

Intervention (if applicable)

not applicable

Statistical Analysis

- Factor analysis was used to generate dietary patterns based on predefined food groups.
- The number of factors to retain were determined by eigenvalue, Scree test and factor interpretability.
- The factor score for each pattern was calculated by summing intakes of food groups weighted by their factor loadings, and each woman received a factor score for each identified pattern.
- Good reproducibility of the patterns generated by this method has been demonstrated in a parallel cohort of men.
- The correlations between the scores of the prudent and Western dietary patterns generated from FFQ and diet records were 0.52 for the prudent pattern and 0.74 for the Western pattern.
- Cox proportional hazard models were used to examine the associations between major dietary patterns and diabetes risk.
- Cumulative averages of dietary pattern scores were calculated from repeated dietary measurements to reduce the influence of random error and to best represent long-term dietary intake.
- Dietary intake in 1984 was used to predict diabetes occurrence from 1984 to 1986, and the average of 1984 and 1986 intake was used to predict risk from 1986 to 1990, and so on.
- Regression analyses were adjusted for potential confounders.
- Additional adjustment for waist-hip ratio among women with the available data was made to minimize confounding by adiposity.

Data Collection Summary:

Timing of Measurements

- The cohort was followed from 1984 to 1998 using biennial mailed questionnaires.
- In 1984, a 116-item FFQ was used as baseline for this study.
- Similar FFQs were sent to the women in 1986, 1990, and 1994. The proportions with a missing FFQ in 1986, 1990, and 1994 were 17%, 16% and 14%, respectively.
- Validation studies for this cohort revealed correlation coefficients between 1986 FFQ and diet records obtained in 1986 were good: 0.68 for saturated fat, 0.76 for vitamin C, and 0.73 for dietary cholesterol.
- Women reporting a diagnosis of diabetes in the biennial questionnaires were sent supplementary questionnaires asking about symptoms, diagnostic tests and treatment to confirm the diagnosis.
- The criteria for diabetes classification were consistent with those of the National Diabetes Data

Group. A validation study showed a high level of accuracy in self-reporting of diabetes.

Dependent Variables

- Incident type 2 diabetes

Independent Variables

- Prudent and Western dietary patterns

Control Variables

- Age, BMI, physical activity, alcohol intake, smoking status and caloric intake
- Family history of diabetes, history of hypercholesterolemia, hormone therapy use, history of hypertension, and missing FFQ

Description of Actual Data Sample:

Initial N: 121,700 women at study initiation in 1976

Attrition (final N): 69,554 for the analyses indicating 43% dropout rate

Age: Participants were aged 38 to 63 years at baseline in 1984

Ethnicity: not described

Other relevant demographics: not described

Anthropometrics: Whether groups were significantly different on BMI were not described.

Location: 11 U.S. states

Summary of Results:

Key Findings:

- 2699 incident cases of type 2 diabetes were identified during 14 years of follow-up.
- The prudent pattern was characterized by higher intakes of fruits, vegetables, legumes, fish, poultry, and whole grains, while the Western pattern included higher intakes of red and processed meats, sweets and desserts, french fries, and refined grains.
- After adjusting for potential confounders, a relative risk for diabetes of 1.49 (95% CI, 1.26-1.76, $P < 0.001$ for trend) when comparing the highest to lowest quintiles of the Western pattern.
- Positive associations were also observed between type 2 diabetes and red meat and other processed meats.
- The relative risk for diabetes for every 1-serving increase in intake is 1.26 (95% CI, 1.21-1.42) for red meat, 1.38 (95% CI, 1.23-1.56) for total processed meats, 1.73 (95% CI, 1.39-2.16) for bacon, 1.49 (95% CI, 1.04-2.11) for hot dogs, and 1.43 (95% CI, 1.22-1.69) for processed meats.

Author Conclusion:

- The Western pattern, especially a diet higher in processed meats, may increase the risk of type 2 diabetes in women.

Reviewer Comments:

The observed associations were valid due to several reasons. First, this is a large prospective cohort observational study. Thus, there was little concern that subjects were not a representative sample. Second, because follow-up was complete greater than 95% up to 1994, I am not too worried that specific methods of handling withdrawals were not adequately described. Third, dietary intakes were collected multiple times throughout the study period. Finally, measures of dependent and independent variables were validated for this cohort. However, blinding was not described in this study.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	Was the research question clearly stated?	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes

2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	Were study groups comparable?	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	No
4.1.	Were follow-up methods described and the same for all groups?	No
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	No
4.4.	Were reasons for withdrawals similar across groups?	No
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A

5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	No
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes

8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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